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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/759,037	01/20/2004	Yosef Shaul	27169	7306

7590 06/15/2005

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EXAMINER	
HILL, MYRON G	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 06/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/759,037	SHAUL ET AL.	
	Examiner	Art Unit	
	Myron G. Hill	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 March 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 4* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 4* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

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DETAILED ACTION

This action is in response to the paper filed March 22, 2005.

Claims 1 and 4 are under consideration.

Rejections Withdrawn

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claims 1 and 4 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The method lacks a conclusion step which indicates that inhibiting has occurred and indicates how inhibition is determined or what the result is.

Applicant has amended the claims and the rejection is withdrawn.

New Rejection Necessitated By Amendment

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in

the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The claim has been amended to recite "at least 90%".

Applicant argues in the response that the amendment finds support in *In re Wertheim*.

The Office acknowledges the citation but there must be support for that limitation in the specification. The passage in the MPEP that cites this case (2163, ranges) states that the value the range is changed to has support in the specification for that value. The support may be found in the data presented in the figures and tables, for example, not just literally in the disclosure.

The examiner does not see support for this value in the specification.

Applicant is requested to point it out.

Claim Rejections - 35 USC § 112

Claims 1 and 4 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID# 4 binding to a portion of HBV preS1 (as defined by SEQ ID# 8 and 9), does not reasonably provide enablement for in vivo activity, prevention of disease, and 90% homologous regions, portions, or whole SEQID# 4 that function to inhibit attachment. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Applicant argues that Mitsuya *et al.* relate to single drug therapy only in terms of lack of enablement, and that the drug Mitsuya *et al.* have a different mode of action. Also, that the limitation of % identity is changed to 90%.

Applicant's arguments have been fully considered and not found persuasive.

The claims read on in vivo treatments, portions and 90% sequence variance.

Applicant's arguments over Mitsuya *et al.* are considered but not entirely correct.

The rejection points to the requirement for levels of drug required for treatment of humans as stated in Mitsuya *et al.* and the instant specification provides no guidance as to claimed method's ability work in vivo. There is no showing in the specification that the results in vitro will be the same as in vivo. There is no showing of portions or variant regions that work.

Thus, it would require undue experimentation to use the invention as now claimed.

Rejections Maintained

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant has amended the claim to 90% identity and argues that it is in the range of functional equivalents.

Applicant's arguments have been fully considered and not found persuasive.

The limitation still provides a large variety of possible peptides and there is no specific guidance on what positions can be changed.

Applicant has not provided any examples of peptides that are functionally equivalent or a range of them to cover the genus of peptides now claimed.

The rejection is maintained.

Claim Rejections - 35 USC § 102

Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by Jacobs *et al.* (US 2001/0016650, published 23 August 2001, SEQ ID# 6 is found in application 08/885610, filed 30 June 1997).

Applicant argues that the prior art protein (which is 99% homologous) is immunosuppressive and thus teaches away from the claimed method.

Applicants arguments have been fully considered and not found persuasive.

The claim is not limited to in vivo therapies.

The prior art discloses that the proteins are not limited to in vivo therapies and can be used in vitro (paragraph 0091).

The rejection is maintained.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 571-272-0901. The examiner can normally be reached on 8:30 am-5 pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Myron G. Hill
Patent Examiner
8 June 2005

James C. Housel 6/13/05
JAMES HOUSEL
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600